UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 4 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF HARRY JOHNSON, JR., M.D.

Harry Johnson, M.D., is a board-certified urogynecologist with more than three decades of experience in the field. Ethicon designated Dr. Johnson to offer general opinions, and he has authored three reports in this Wave 4 litigation—one regarding the Prolift and Gynemesh PS, and the other two regarding TVT and TVT-O. *See generally* General Expert Report (Prolift/Gynemesh PS) of Harry Johnson, Jr. M.D. ("Johnson Prolift Report") [Dkt. 3661-2]; Ex. A, Expert Report of Harry Johnson, M.D. (June 3, 2016); Ex. B, Expert Report of Harry Johnson, M.D. (June 15, 2016). Plaintiffs' Motion and Brief [Dkt. 3650 & 3661] address only Dr. Johnson's Prolift/Gynemesh PS Report.

Specifically, Plaintiffs contend (1) that Dr. Johnson lacks the qualifications to offer opinions regarding the adequacy of the devices' IFUs because he lacks expertise in the areas of regulatory compliance and compliance with Ethicon's internal corporate procedures; (2) that Dr. Johnson's opinions regarding his clinical experience with the products is unreliable because he

does not maintain a registry of surgeries and outcomes; and (3) that Dr. Johnson lacks the qualifications to offer opinions about the "design" of the devices because he lacks expertise in the area of design process.

As an initial matter, Plaintiffs challenge neither Dr. Johnson's qualification nor his methodology in relation to the vast majority of his proffered opinions. Instead, Plaintiffs challenge three discrete opinions from Dr. Johnson's report. Plaintiffs' silence in regard to the remainder of his opinions is a testament to Dr. Johnson's credentials and the reliability of his methodology.

None of Plaintiffs' three specific challenges has merit:

First, Dr. Johnson is imminently qualified to offer the IFU opinions expressed in his report. Plaintiffs frame their challenge to his warnings opinions around the analytical fallacy that an expert must have expertise in regulatory or internal procedure compliance to offer such opinions. But Dr. Johnson's opinions regarding the adequacy of the devices' IFUs does not touch upon any regulatory requirements or internal Ethicon procedures. Rather, Dr. Johnson—consistent with the law and this Court's prior rulings—merely identifies the risks associated with non-mesh pelvic floor surgeries, identifies the risks associated with mesh pelvic floor surgeries, and opines as to whether the IFUs adequately warn of the risks unique to the mesh surgeries. Dr. Johnson is imminently qualified to offer such opinions.

Second, the Court has previously and repeatedly rejected Plaintiffs' contention that a physician must keep a registry of his patients and their surgical outcomes in order to testify regarding his experience with the product.

Third, Plaintiffs' attack Dr. Johnson's "design" opinions is premised on nothing more than a language trick. Plaintiffs contend that Dr. Johnson cannot offer "design" opinions because

he lacks expertise in the area of design process. But Dr. Johnson's "design" opinions have nothing to do with Ethicon's process of designing the devices. Instead, his "design" opinions go to the adequacy of the physical design of the devices. Plaintiffs' design process attack is misplaced, and they make no arguments that Dr. Johnson's opinions about the physical design of the devices are inadmissible.

For these reasons, Plaintiffs' motion to limit Dr. Johnson's testimony should be denied.

ARGUMENT AND AUTHORITIES

Dr. Johnson's testimony is admissible. He is qualified to offer his opinions and has applied a reliable methodology to arrive at his opinions. Dr. Johnson's opinions are relevant to the facts at issue in this litigation. Accordingly, Dr. Johnson's testimony complies with the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and the Federal Rules of Evidence and should be admitted.

I. Standard for Admissibility of Expert Opinion Testimony

Ethicon incorporates by reference the standard of review for Daubert motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

II. Dr. Johnson Is Qualified to Opine on the Adequacy of the Devices' IFUs

Plaintiffs argue that Dr. Johnson lacks the necessary qualifications to offer any opinions regarding the Prolift's and Gynemesh PS's IFUs because he lacks expertise in regulatory compliance and Ethicon's internal standards. *See* Pls.' Br. [Dkt. 3661] at 3-4. Plaintiffs' argument is premised on a fallacy. An expert need not be an expert in the field of regulatory compliance or internal company standards to opine regarding the adequacy of the IFU.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of

labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec.16, 2011)).

The important question here is whether Dr. Johnson's testimony is consistent with the law to be applied to the case, and not whether he himself could articulate the governing legal standard. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D.W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of person whose use is at issue in the particular case. *Johnson v. American Standard, Inc.*, 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

This limitation on the duty to warn is recognized in medical device cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.10(c) (emphasis added); *see also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue here restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. For example, the Prolift IFU says "[u]sers should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbale meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems." Ex. C, Prolift IFU (ETH.MESH.02341454) at 6.

So the important question with respect to Plaintiffs' failure to warn claim is what "hazards" were "commonly known" to surgeons familiar with traditional non-mesh pelvic floor surgery and mesh pelvic floor surgery before Prolift was introduced.

Dr. Johnson is qualified by his experience and his examination of the literature to identify the risks that are commonly known and give the opinion that the IFU adequately discloses those that might not be. That is precisely what he has done here. In his report, Dr. Johnson (1) identifies the risks associated with non-mesh surgeries, (2) identifies the risks associated with mesh surgeries, (3) identifies which of those risks are unique to mesh surgeries, and (4) reviews the IFUs to determine if Ethicon warned surgeons of the risks unique to mesh surgeries. *See* Johnson Prolift Report [Dkt. 3661-2] at 11-17. Dr. Johnson identified only one risk that was unique to mesh surgeries—the risk of "mesh erosion/extrusion/exposure." *Id.* at 16.

This Court's prior rulings—*Tyree* and *Bellew*—are distinguishable. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree*, 54 F. Supp. 3d at 584 (S.D.W. Va. 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014). While a single physician's experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Johnson has done here. As indicated in Dr. Johnson's Prolift Report, he engaged in a broad review of the medical literature, including meta-analyses that compiled the results from various studies. *See* Johnson Prolift Report [Dkt. 3661-2] at 11-15. He then compiled a list comparing the risks of mesh surgeries to non-mesh surgeries, *see id.* at 16 (Table 1), and concludes that "the only risk associated with the use of transvaginal mesh in the surgical treatment of pelvic organ prolapse that is not also a risk of native tissue repair is mesh erosion/extrusion/exposure." *Id.* at 16. He goes on to note that the subject IFUs specifically inform physicians that "Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction." *Id.* at 16-17.

Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Johnson's conclusion can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

Plaintiffs' citation to *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D.W. Va. 2013), is misplaced. In *C.R. Bard*, the plaintiffs designated Bob Shull, M.D., to opine that the defendant "should have investigated and resolved a complication of this magnitude [i.e., postoperative pain] prior to marketing a permanent implanted medical device." *Id.* at 611. As noted by the Court, Dr. Shull did not identify any basis for his opinion about what the defendant "should have" done. *Id.* Here, Dr. Johnson is not offering an opinion regarding what Ethicon should or should not have done from either a regulatory or internal compliance perspective. Instead, Dr. Johnson identifies the risks associated with non-mesh surgery, compares them to the risks associated with mesh surgery, and opines that the IFUs adequately warned surgeons of the risks unique to the devices.

II. Dr. Johnson's Opinions Regarding His Personal Experience with the Devices Are Reliable

Plaintiffs argue that Dr. Johnson should not be allowed to testify regarding his experience with the subject products because his experiences are "unsupported by any meaningful statistical information or analysis." Pls.' Br. [Dkt. 3661] at 4. In making this argument, Plaintiffs cite to no legal authority and wholly ignore the Court's prior rulings on similar arguments.

Dr. Johnson's failure to maintain a registry to track precisely his personal experiences with patients does not render his testimony unreliable. In rejecting a similar argument in another case, this Court found as follows:

> The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. The plaintiff's argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions.

Ex. D, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D.W. Va. Nov. 20, 2014); *see also Winebarger*, 2015 WL 1887222, at *34 (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device'"); *Trevino v. Boston Scientific Corp.*, Civ. A. No. 2:12-cv-01617, 2016 WL 2939521, at *33 (S.D.W. Va. May 19, 2016) (same).

Dr. Johnson applied a sound methodology in formulating his opinions regarding the safety and utility of the devices at issue based on his personal experience and his thorough review of peer-reviewed publications. This Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp,* 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (expert's opinion about safety and efficacy was reliable where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, *36 (S.D.W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare).

For these same reasons, the Court should reject Plaintiffs' argument here. Indeed, physicians routinely counsel patients considering surgery on the physicians' rough perception of their own complication rates, and Dr. Johnson's inability to confirm his understanding of his complication rates with precision does not render his experience unhelpful or unscientific.

III. Dr. Johnson's Opinions Regarding the Design of the Devices Are Reliable

Plaintiffs' attack on Dr. Johnson's "design" opinions is a farce and merely the latest example of what the Court deemed a "plague" of "confusion about what constitutes a design opinion." Mem. Op. & Order (*Daubert* Motion re: Teresa Irwin, M.D.) [Dkt. 2719] at 6. Notably absent from Plaintiffs' Brief is any citation to a specific "design" opinion being challenged. *See* Pls.' Br. at 6-10. Instead, Plaintiffs point the Court only to Dr. Johnson's summary opinion that the subject device is not defective in design. *See id.* (quoting Johnson Prolift Report at 5).

Plaintiffs then launch into a four-page attack of Dr. Johnson contending that he cannot offer "design" opinions because he did not review the documents regarding Ethicon's design process. Though not expressly stated, it is clear from the context of the challenge that Plaintiffs are seeking to exclude all "design" opinion testimony from Dr. Johnson because of his lack of familiarity with the process by which Ethicon went about designing the devices. *See* Pls.' Br. [Dkt. 3661] at 6-7. For example, in support of their attack, Plaintiffs cite testimony that Dr. Johnson does not know the names of the Ethicon employees who designed the product and that he did not review the 510(k) application. *Id.* at 9-10.

Contrary to Plaintiffs' arguments, Dr. Johnson is not offering any opinions regarding the design process. *See generally* Johnson Prolift Report. Rather, Dr. Johnson's opinions relate to the physical properties of the devices—the finished product, not the process. *See id.* at 14-15 (discussing the physical properties of the Prolift device). Plaintiffs make no arguments against Dr. Johnson's qualifications or methodology in arriving at his opinions regarding the physical design of the devices.

This conflation of the term "design" has become a routine stunt for Plaintiffs in this litigation. And they persist in this ploy despite the Court providing unambiguous "clarification" on the topic:

> At first glance, it seems the plaintiffs want to prevent Dr. Irwin from providing any opinions that even mention the word "design." But the mere utterance of a single word is not an incantation that transforms an opinion about one thing into something else.
>
> A close, contextual reading of the transvaginal mesh cases where this issue has been raised before reveals the heart of the plaintiffs' objections. In this motion—and several others—the plaintiffs argue that the expert at issue lacks the particularized skill, knowledge, experience, education, or training that is necessary to provide opinions about the process of designing a product. Opinions of this sort include, for example, opinions about pre-marketing product testing and product development. But upon review, I find Dr. Irwin has not expressed any opinions about the process of designing a product.

Mem. Op. & Order (*Daubert* Motion re: Teresa Irwin, M.D.) [Dkt. 2719] at 6.

Plaintiffs' reliance on *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D.W. Va. Apr. 24, 2015), is misplaced. There, the plaintiffs designated Dr. Shull to opine on the design process. Specifically, the plaintiffs sought to have Dr. Shull offer opinions testimony regarding the defendant's alleged "failure to 'follow its own internal procedures'" and the defendant's alleged "lack of due diligence in the design and development of the [device.]" *Id.* at *14. He also sought to opine that the defendant's internal design procedures were "departures from the norm." *Id.* Despite his attempt to opine regarding the internal design process of the defendant, Dr. Shull had no "reliable, demonstrated knowledge of [the defendant's] internal design procedures." *Id.* Accordingly, the Court precluded Dr. Shull from criticizing a process he never reviewed. Dr. Johnson's "design" opinions bear no resemblance to the design process opinions Dr. Shull attempted to peddle.

Finally, to the extent that Plaintiffs argue that Dr. Johnson's "design" opinions should be excluded because he did not review some unnamed "medical society statements that discuss the design and safety," such arguments go to the weight, not admissibility, of Dr. Johnson's testimony. *See Carroll v. Boston Scientific Corp.*, Civ. A. No. 2:13-cv-11601, 2016 WL 2939523, at *7 (S.D.W. Va. May 19, 2016) (expert's failure to consider document goes to weight, not admissibility, of opinion testimony).

CONCLUSION

For the above reasons, Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson respectfully request that this Court enter an order denying Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Harry Johnson, M.D. [Dkt. 3650 & 3661].

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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